CLEAN COPY OF PENDING CLAIMS OF U.S. SERIAL NO. 09/155,642

- 1. A solid composition comprising a biologically active agent dissolved in a carrier system, wherein the carrier system includes an unsaturated fatty acid alcohol in combination with an alkylene glycol selected from propylene glycol, butylene glycol, dipropylene glycol and/or dibutylene glycol as a solvent for the active agent and a viscosity enhancing agent for imparting a solid consistency to the composition, said alkylene glycol being present in an amount that gives mutual dissolution with said unsaturated fatty acid alcohol as well as dissolution of said active agent.
- 2. A composition as claimed in Claim 1, wherein the amount of said alkylene glycol is more than 12% by weight, based on the total weight of the carrier system.
- 3. A composition as claimed in Claim 2, wherein the amount of said alkylene glycol is at least 15% by weight.
- 4. A composition as claimed in Claim 1, wherein said unsaturated fatty acid alcohol is an unsaturated C_{16} - C_{20} -fatty acid alcohol.
- 6. A composition as claimed in Claim 1, wherein the stiffening agent is a viscosity enhancing agent capable of imparting a soft and erodible consistency to the composition.

January 4, 2000 Clean Copy of Pending Claims of U.S. Serial No. 09/155,642

- 7. A composition as claimed in Claim 1, wherein the biologically active agent is a lipophilic compound.
- 8. A composition as claimed in Claim 7, wherein the biologically active compound is selected from steroids, including corticosteroids, sex hormones, including androgens and estrogens and derivatives thereof, vitamins, including vitamins A, D2, D3, E, K and derivatives thereof, biologically active lipids, fatty acids, antibiotics and antimicrobials, including antivirals, antibacterials, antiprotozoals and antifungals, and local anesthetics.
- 9. A composition as claimed in Claim 8, wherein the biologically active compound is selected from fluorinonide, omega-3-fatty acid and azelaic acid and salts and esters thereof.
- 10. A composition as claimed in Claim 8, wherein the biologically active compound is clobetasol or a salt or an ester thereof.
- 11. A composition as claimed in Claim 1, wherein the alkylene glycol is propylene glycol.

- 12. A composition as claimed in Claim 1, wherein the solvent additionally comprises a C_1 - C_6 -alkanol ester of a fatty acid and/or a C_1 - C_6 -alkanol ester of sorbic acid.
- 13. A composition as claimed in Claim 12, wherein said additional solvent comprises propyl myristate, palmitate, oleate, stearate and/or laurate, and/or the propyl ester of sorbic acid.
- 14. A composition as claimed in Claim 13, wherein said additional solvent is isopropylpalmitate.
- 15. A composition as claimed in Claim 1, wherein the viscosity enhancing agent is a waxy substance.
- 16. A composition as claimed in Claim 15, wherein the waxy substance comprises a natural and/or synthetic wax; a fat; a glycol ester of a C₁₈-C₃₆ fatty acid; or a mixture of two or more such compounds.
- 17. A composition as claimed in Claim 16, wherein the waxy substance comprises a combination of a natural or synthetic wax and a triglyceride and/or a glycol ester.

- 18. A composition as claimed in Claim 1, wherein the carrier system also comprises a plasticizing oil capable of plasticizing the viscosity enhancing agent and reducing the viscosity of the carrier system.
- 19. A composition as claimed in Claim 18, wherein the plasticizing oil is selected from low molecular weight aliphatic acids and alcohols.
- 20. A composition as claimed in Claim 18, wherein the amount of solvent is within the range of 20-85% by weight, the amount of viscosity enhancing agent is within the range of 15-80% by weight and the amount of plasticizing oil is within the range of 0-30% by weight, based on the total weight of the carrier system.
- 21. A composition as claimed in Claim 20, wherein the amount of solvent is within the range of 25-75% by weight, the amount of viscosity enhancing agent is within the range of 15-55% by weight and the amount of plasticizing oil is within the range of 0-30% by weight.
- 22. A composition as claimed in Claim 1, wherein the amount of said alkylene glycol is within the range of 12-23% by weight.

January 4, 2000 Clean Copy of Pending Claims of U.S. Serial No. 09/155,642

- 23. A composition as claimed in Claim 12, wherein the weight ratio of unsaturated fatty acid alcohol: additional solvent is within the range of 1:2 to 5:1.
- 24. A composition as claimed in Claim 1, wherein the biologically active agent is present in a concentration of up to the solubility limit thereof in the carrier system.
- 25. A composition as claimed in Claim 1, wherein the concentration of the biologically active agent is 0.01-10% by weight, based on the weight of the carrier system.
- 26. A composition as claimed in Claim 1, wherein said composition is a stick composition.
- 27. A composition as claimed in Claim 1, wherein said biologically active agent is a therapeutically or prophylactically active agent.
- 28. A composition as claimed in Claim 27, for topical application to the skin of a mammal, wherein the composition has a viscosity that is adapted for such application.

January 4, 2000 Clean Copy of Pending Claims of U.S. Serial No. 09/155,642

- 32. A process for the preparation of a biologically active composition as claimed in Claim 1, comprising dissolving the biologically active agent in said solvent therefor, combining the resulting solution with a viscosity enhancing agent so as to impart a solid consistency to said solution and shaping the resulting composition into a desired form.
- 33. A method of prophylactic or therapeutic treatment of a dermatological condition comprising topically applying a prophylactically or therapeutically effective amount of an active agent containing solid composition according to Claim 1, wherein the active agent is suitable for treatment or prophylaxis of a dermatological condition.
- 34. The method of Claim 33, wherein the active agent is selected from the group consisting of a steroid, vitamin, biologically active lipid, fatty acid, antimicrobial, and anesthetic.
- 35. The method of Claim 33, wherein the active agent is selected from the group consisting of a corticosteroid, sex hormone, vitamin A, vitamin B2, vitamin B3, vitamin E, vitamin K, an antibiotic, an antiviral, anti-protozoal, antifungal, and an amide local anesthetic.

- 36. The method of Claim 33, wherein the active agent is selected from the group consisting of clobetasol or a salt or ether thereof, and beta-methasone or a salt or ester thereof.
- 37. The method of Claim 36, wherein the active agent is clobetasol propionate, methasone-17-valerate or betamethasonedipropionate.
- 38. A composition as claimed in Claim 1, wherein said unsaturated fatty acid alcohol is an unsaturated C18-fatty acid alcohol.
- 39. A composition as claimed in Claim 38, wherein said unsaturated C_{18} -fatty acid alcohol is selected from oleyl alcohol, ricinolyl alcohol, linelyl alcohol and/or linelyl alcohol.
- 40. A composition as claimed in Claim 1, wherein the biologically active agent is a lipophilic drug.
- . 41. A composition as claimed in Claim 7 wherein the biologically active compound is lipophilic anesthetic of the amide type.

- 42. A composition as claimed in Claim 10, wherein the biologically active compound is clobetasol propionate.
- 43. A composition as claimed in Claim 15, wherein the waxy substance comprises a natural and/or synthetic wax that is a monoester of a long-chain carboxylic acid with a long-chain alcohol, and the fat is a triglyceride of a C_{18} - C_{36} fatty acid.
- 44. A composition as claimed in Claim 18, wherein the plasticizing oil is selected from low molecular weight branched chain aliphatic acids and alcohols.
- 45. A composition as claimed in Claim 18, wherein the plasticizing oil is fluid lanoline.
- 46. A composition as claimed in Claim 20, wherein the amount of solvent is within the range of 40-60% by weight, the amount of viscosity enhancing agent is within the range of 25-50% by weight, and the amount of plasticizing oil is within the range of 2-20% by weight.
- 47. A composition as claimed in claim 1, wherein the amount of said alkylene glycol is within the range of 15-23% by weight.

- 48. A composition as claimed in claim 1, wherein the amount of said alkylene glycol is within the range of 12-20% by weight.
- 49. A composition as claimed in claim 1, wherein the amount of said alkylene glycol is within the range of 15-20% by weight.
- 50. A composition as claimed in Claim 12, wherein the weight ratio of unsaturated fatty acid alcohol: additional solvent is within the range of 1:2 to 3:1.
- 51. A composition as claimed in Claim 12, wherein the weight ratio of unsaturated fatty acid: additional alcohol is within the range of 1:2 to 2:1.
- 52. A composition as claimed in Claim 1, wherein the concentration of the biologically active agent is 0.02-5% by weight based on the weight of the carrier system.
- 53. A composition as claimed in Claim 1, wherein the biologically active compound is beta-methasone, or a salt or ester thereof.
- 54. A composition according to Claim 1, wherein the biologically active compound is beta-methasone-17-valerate or betamethasonedipropionate.